

ATTACHMENT TO NOTICE OF ALLOWABILITY

Request for Continued Examination

1) A request for continued examination under 37 C.F.R. 1.114, including the fee set forth in 37 C.F.R. 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 C.F.R. 1.114, and the fee set forth in 37 C.F.R. 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 C.F.R. 1.114. Applicants' submission filed on 12/18/09 has been entered.

Applicants' Response

2) Acknowledgment is made of Applicants' amendment filed 12/18/09 in response to the final Office Action mailed 08/18/09.

Examiner's Amendment

3) An Examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to Applicants, an amendment may be filed as provided by 37 C.F.R. 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee. The authorization to prepare this Examiner's amendment was provided by attorney Beth Arnold (registration number # 35430) in a telephonic interview on 04 January 2010.

This application has been amended as indicated below.

Claim 22 has been amended as indicated below.

--Claim 22 (Currently amended). A method for detecting a symptomatic *Streptococcus pneumoniae* infection in a human subject of age 12 years or less comprising:

applying, to a sample receiving zone at an end of a bibulous test strip, a urine sample obtained from the human subject of age 12 years or less;

allowing the urine sample to flow laterally along the bibulous test strip;

mobilizing tagged purified antibodies capable of binding the C-polysaccharide antigen of *Streptococcus pneumoniae*, the tagged purified antibodies having been present immediately ahead of the sample receiving zone on the bibulous test strip and rendered flowable by contact

with the urine sample, to form a mixture comprising the urine sample and the mobilized tagged purified antibodies;

allowing the binding of the tagged purified antibodies and the C-polysaccharide antigen, to form conjugates of the tagged purified antibodies and the C-polysaccharide antigen in the mixture;

allowing the mixture comprising the conjugates of the tagged purified antibodies and the C-polysaccharide antigen to flow further along the bibulous test strip;

allowing the binding of the conjugates of the tagged purified antibodies and the C-polysaccharide antigen to scrub line antibodies specific for the conjugates of the tagged purified antibodies and the C-polysaccharide antigen, the scrub line antibodies having been immobilized in at least one scrub line along the bibulous test strip;

allowing the mixture comprising the conjugates of the tagged purified antibodies and the C-polysaccharide antigen to flow downstream of the at least one scrub line; and allowing the binding of capture line antibodies specific for the conjugates of the tagged purified antibodies and the C-polysaccharide antigen, the capture line antibodies having been immobilized in a capture line downstream of the at least one scrub line, to the conjugates of the tagged purified antibodies and the C-polysaccharide antigen, wherein color formation in the downstream capture line resulting from the binding of the conjugates of the tagged purified antibodies and the C-polysaccharide antigen to the immobilized capture line antibodies specific for the conjugates of the tagged purified antibodies and the C-polysaccharide antigen is indicative of [[a]] the symptomatic *Streptococcus pneumoniae* infection in the subject.--

Status of Claim(s)

4) Claim 22 is pending.

Claim 22 has been amended as indicated above via this Examiner's amendment.

Rejection(s) Withdrawn

5) The rejection of claim 22 made in paragraph 11 of the Office Action mailed 06/05/09 and maintained in paragraph 6 of the Office Action mailed 08/18/09 under 35 U.S.C. § 112, first paragraph, as containing inadequate written description, is withdrawn upon further consideration. Applicants submit that Example 3 of the specification demonstrates performing of the claimed

method with a scrub line antibody concentration of 0.3 mg/ml which detected 87.5% of positive samples and with a scrub line concentration of 0.4 mg/ml which detected 83% of positive samples.

Remarks

- 6)** Claim 22, now renumbered as claim 1, has been allowed.
- 7)** Papers related to this application may be submitted to Group 1600, AU 1645 by facsimile transmission. The Fax number for submission of amendments, responses and/or papers is (571) 273-8300, which receives transmissions 24 hours a day and 7 days a week.
- 8)** Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAG or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.Mov>. Should you have questions on access to the Private PAA system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (in USA or CANADA) or 571-272-1000.
- 9)** Any inquiry concerning this communication or earlier communications from the Examiner should be directed to S. Devi, Ph.D., whose telephone number is (571) 272-0854. A message may be left on the Examiner's voice mail system. The Examiner can normally be reached on Monday to Friday from 7.15 a.m. to 4.15 p.m. except one day each bi-week, which would be disclosed on the Examiner's voice mail system.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Robert Mondesi, can be reached on (571) 272-0956.

/S. Devi/
Primary Examiner
AU 1645

January, 2010